I

106TH CONGRESS
2D SESSION

H. R. 5198

To protect the health and welfare of children involved in research.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 18, 2000

Ms. DEGETTE (for herself and Mr. LATOURETTE) introduced the following bill; which was referred to the Committee on Commerce

---

A BILL

To protect the health and welfare of children involved in research.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Children's Research Protection Act''.

SEC. 2. FINDINGS, PURPOSES, AND DEFINITION.

(a) FINDINGS.—Congress makes the following findings:

(1) Children are the future of the Nation and the preservation and improvement of child health is in the national interest.

(2) The preservation and improvement of child health may require the use of pharmaceutical products.

(3) Currently only 1 out of 5 drugs on the market in the United States have been approved for use by children. The enactment of the provisions of the Food and Drug Administration Modernization Act (Public Law 105–115) relating to pediatric studies of drugs, however, is expected to increase the pediatric testing of pharmaceuticals and thus to increase the numbers of children involved in research.

(4) Children are a vulnerable population and thus need additional protections for their involvement in research relative to adults. Yet, current Federal guidelines for the protection of children involved in research have not been updated since 1981. Only research funded by the Department of Health and Human Services and the Department of Education have additional regulations for the protection of children in research. These regulations have not been adopted by other Federal agencies, are not required for research regulated by the Food and Drug Administration, and do not apply to other non-federally funded research.

(5) Currently, in the United States, there is a shortage of pharmacologists trained to address the unique aspects of developing therapies for children. There are fewer than 200 academic-based clinical pharmacologists in the United States, of which 20 percent or fewer are pediatricians. Currently, only 20 physicians complete clinical pharmacology specialty training programs each year, and of these, only 2 or fewer specialize in pediatric pharmacology.

(b) PURPOSES.—It is the purpose of this Act to—

(1) ensure the adequate and appropriate protection of children involved in research by—

(A) reviewing and updating as needed the Federal regulations that provide additional protections for children participating in research as contained in subpart D of part 45 of title 46, Code of Federal Regulations;

(B) extending such subpart D to all research regulated by the Secretary of Health and Human Services; and

(C) requiring that all Federal agencies adopt regulations for additional protections for children involved in research that is conducted, supported, or regulated by the Federal Government; and

(2) ensure that an adequate number of pediatric clinical researchers, including pediatric pharmacologists, are trained and retained, in order to meet the increased demand for expertise in this area created by the pediatric studies provisions of the Food and Drug Administration Modernization Act (Public Law 105–115), so that all children have access to medications that have been adequately and properly tested on children.

(c) DEFINITION.—In this Act, the term ''pediatric clinical pharmacologist'' means an individual—

(1) who is board certified in pediatrics; and

(2) who has additional formal training and expertise in human pharmacology.

SEC. 3. REVIEW OF REGULATIONS.

(a) REVIEW.—By not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall have conducted a review of the regulations under subpart D of part 45 of title 46, Code of Federal Regulations, considered any modifications necessary to ensure the adequate and appropriate protection of children participating in research, and implement any modifications necessary to ensure human subject protections of children in research.

(b) AREAS OF REVIEW.—In conducting the review under subsection (a), the Secretary of Health and Human Services shall consider—

(1) the appropriateness of the regulations for children of differing ages and maturity levels, including legal status;

(2) the definition of ''minimal risk'' and ''a minor increase over minimum risk'' and the manner in which such definition varies for a healthy child as compared to a child with an illness;

(3) the definitions of ''assent'' and ''permission'' for child clinical research participants and their parents or guardians and of ''adequate provisions'' for soliciting assent or permission in research as such definitions relate to the process of obtaining the informed consent of children participating in research and the parents or guardians of such children;

(4) the definitions of ''direct benefit to the individual subjects'' and ''generalizable knowledge about the subject's disorder or condition'';

(5) whether or not payment (financial or otherwise) may be provided to a child or his or her parent or guardian for the participation of the child in research, and if so, the amount and type given;

(6) the expectations of child research participants and their parent or guardian for the direct benefits of the child's research involvement;

(7) safeguards for research involving children conducted in emergency situations with a waiver of informed assent;

(8) parent and child notification in instances in which the regulations have not been complied with;

(9) compliance with the regulations in effect on the date of enactment of this Act, the monitoring of such compliance, and enforcement actions for violations of such regulations; and

(10) the appropriateness of current practices for recruiting children for participation in research.

(c) CONSULTATION.—In conducting the review under subsection (a), the Secretary of Health and Human Services shall consult broadly with experts in the field, including pediatric pharmacologists, pediatricians, bioethics experts, clinical investigators, institutional review boards, industry experts, and children who have participated in research studies and the parents or guardians of such children.

(d) CONSIDERATION OF ADDITIONAL PROVISIONS.—In conducting the review under subsection (a), the Secretary of Health and Human Services shall consider and,

not later than 6 months after the date of enactment of this Act, report back to Congress concerning—

(1) whether the Secretary should establish national data and safety monitoring boards to review adverse events associated with research involving children; and

(2) whether the institutional review board oversight of clinical trials involving children is adequate to protect the children.

SEC. 4. REQUIREMENT FOR ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED IN RESEARCH.

(a) IN GENERAL.—Notwithstanding any other provision of law, not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall require that all research involving children that is conducted, supported, or regulated by the Department of Health and Human Services be in compliance with subpart D of part 45 of title 46, Code of Federal Regulations.

(b) OTHER FEDERAL AGENCIES.—Not later than 12 months after the date of enactment of this Act, all Federal agencies shall have promulgated regulations to provide additional protections for children involved in research.

(c) REQUIREMENTS FOR INSTITUTIONAL REVIEW BOARDS.—When reviewing a proposal that will include a

child as a subject of research, the Institutional Review Board involved shall include members who are experts in the issues involving pediatric research. Such members shall be allowed to fully participate in the Board review process and have the same voting rights as other Board members.

SEC. 5. GRANTS FOR PEDIATRIC PHARMACOLOGY.

(a) IN GENERAL.—The Secretary of Health and Human Services shall award grants to qualified academic research institutions and research networks with the appropriate expertise to provide training in pediatric clinical pharmacology, such as the Pediatric Pharmacology Research Units of the National Institute of Child Health and Human Development, and the Research Units of the National Institute of Mental Health, to enable such entities to provide fellowship training to individuals who hold an M.D. in order to ensure the specialized training of pediatric clinical pharmacologists.

(b) AMOUNT OF GRANT.—In awarding grants under subsection (a), the Secretary of Health and Human Services shall ensure that each grantee receive adequate amounts under the grant to enable the grantee to fund at least 1 fellow each year for a 3-year period, at a total of $100,000 per fellowship per year.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

SEC. 6. PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM.

Part G of title IV of the Public Health Service Act is amended by inserting after section 487E (42 U.S.C. 288–5) the following:

"SEC. 487F. PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM.

''(a) IN GENERAL.—The Secretary, in consultation with the Director of the National Institute of Child Health and Human Development, shall establish a pediatric research loan repayment program. Through such program—

''(1) the Secretary shall enter into contracts with qualified pediatricians under which such pediatricians will agree to conduct pediatric research, including pediatric pharmacology, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $35,000 of the principal and interest of the educational loans of such pediatricians; and

''(2) the Secretary shall, for the purpose of providing reimbursements for tax liability resulting

from payments made under paragraph (1) on behalf of an individual, make payments, in addition to payments under such paragraph, to the individual in an amount equal to 39 percent of the total amount of loan repayments made for the taxable year involved.

''(b) APPLICATION OF OTHER PROVISIONS.—The provisions of sections 338B, 338C, and 338E shall, except as inconsistent with subsection (a), apply to the program established under such subsection to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established under subpart III of part D of title III.

''(c) AVAILABILITY OF FUNDS.—Amounts made available to carry out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which such amounts were made available.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.''.

SEC. 7. LOAN FORGIVENESS PROGRAM FOR HEALTH CARE PROFESSIONALS CONDUCTING RESEARCH INTO CHILDHOOD DISEASES.

Part G of title IV of the Public Health Service Act, as amended by section 6 of this Act, is amended by inserting after section 487F the following:

"SEC. 487G. LOAN FORGIVENESS PROGRAM FOR HEALTH CARE PROFESSIONALS CONDUCTING RESEARCH INTO CHILDHOOD DISEASES.

''(a) IN GENERAL.—The Secretary, in consultation with the Director of the National Institutes of Health, shall establish a loan forgiveness program for health care professionals conducting research into childhood diseases. Through such program—

''(1) the Secretary shall enter into contracts with qualified health care professionals under which such health care professionals will agree to conduct research into diseases that are prevalent in children in consideration of the Federal government agreeing to repay, for each year of such service, not more than $35,000 of the principal and interest of the educational loans of such health care professionals; and

''(2) the Secretary shall, for the purpose of providing reimbursements for tax liability resulting from payments made under paragraph (1) on behalf

of an individual, make payments, in addition to payments under such paragraph, to the individual in an amount equal to 39 percent of the total amount of loan repayments made for the taxable year involved.

''(b) APPLICATION OF OTHER PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

''(c) AVAILABILITY OF FUNDS.—Amounts made available to carry out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which such amounts were made available.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.''.

SEC. 8. EFFECTIVE DATE.

The provisions of sections 5, 6, and 7 shall take effect on the date that is 6 months after the date of enactment of this Act.

○